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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/202,464 | 03/09/1999 | KOHSUKE KINO | 06501/024001 | 2927 |

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EXAMINER

HUYNH, PHUONG N

| ART UNIT | PAPER NUMBER |
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1644

DATE MAILED: 04/22/2003

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/202,464

Applicant(s)

KINO ET AL.

Examiner

Phuong Huynh

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,7,11,13,14,17 and 20-39 is/are pending in the application.
- 4a) Of the above claim(s) 2, 7, 11, 13-14, 17, 20-28 and 36-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,32-35,38 and 39 is/are rejected.
- 7) ☒ Claim(s) 29-31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 20-21126 6) ☐ Other:

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/21/03 has been entered.
2. Claims 1-2, 5, 7, 11, 13, 14, 17, and 20-39 are pending.
3. Claims 2, 7, 11, 13-14, 17, 20-28 and 36-37 stand withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to non-elected inventions. Applicant is reminded that in order to cancel non-elected inventions, a formal request must be made.
4. Claims 1, 5, 29-35 and 38-39 are being acted upon in this Office Action.
5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
6. Claims 5, and 33-35 stand rejected under 35 U.S.C. 112, first paragraph, containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The term "consisting essentially of" in claims 5 and 33-35 has no support in the specification and the claims as originally filed. Applicant has not point out the support for said "consisting essentially of" comes from. Note, if the composition is intended to be close, it is suggested that the claims be recite "consisting of"; if the composition is intended to be open, it is suggested that the claims be recite "comprising".

Applicants' arguments filed 2/21/03 have been fully considered but are not found persuasive.

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Applicants' position is that (1) the specification as a whole makes it abundantly clear that T cell epitope peptides useful for peptide based immunotherapy of Japanese cypress pollinosis. In light of the disclosure, one of skill in the art would exclude from the claimed compositions only T-cell epitope peptides useful for peptide-based immunotherapy of Japanese cypress pollinosis or pollinosis cross-reactive to with Japanese cypress pollinosis other than the T cell epitopes listed in the claims to which the rejected claims refer. (2) Page 12 of the specification discloses the present invention may be used in combination with other peptide.

In response, it is suggested that the claims be recite "a composition comprising".

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.


8. Claims 1, 5, 32, 38 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by WO94/01560 publication (of record, Jan 1994; PTO 1449).

The WO 94/01560 publication teaches a peptide consisting of NAGVLTCSLSKRC (see reference peptide CJI-35, Fig 13, in particular) which is a part of the claimed peptide SEQ ID NO: 36 shown in Figure 4 from Japanese cypress pollen allergen and has T cell stimulating activity (See claims 119-120 of WO 94/01560 publication, in particular). The WO 94/01560 publication teaches a composition consisting essentially of the reference peptide as an active ingredient and a pharmaceutically acceptable carrier that can reduce the symptoms of Japanese cypress pollinosis or cedar pollinosis (See claims 64 and 68 of WO 94/01560, in particular). The WO 94/01560 publication further teaches a peptide consisting an amino acid sequence YAIGGSSNPTILSEGENSFTA (See Fig 13, peptide CJI-26 of WO 94/01560, claim 119 of WO 94/01560, in particular) that is identical to the claimed peptide of SEQ ID NO: 28. The reference peptide YAIGGSSNPTILSEGENSFTA is a part of a reference peptide consisting of said peptide in tandem joined by a linker such as Arg-Arg (RR) or Lys-Lys (KK) (see page 32, lines 2-25, page 24, line 5-10, in particular) containing at least two T-cell epitopes of Japanese cypress pollen allergen identical to the claimed SEQ ID NO: 28 and has T cell stimulating activity (See claims 119-120 of WO 94/01560, in particular). Thus, the reference teachings anticipate the claimed invention.

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9. Peptides consisting of the amino acid sequence of SEQ ID NO: 4, 6-10, 12-13, 16-18, 27, 29, and 32-35 are free of prior art.
10. Claims 29, 30, and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
11. No claim is allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to "Neon" Phuong Huynh whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.
13. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Phuong N. Huynh, Ph.D.
Patent Examiner
Technology Center 1600
April 21, 2003


CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
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